

Application No. 10/037036  
Page 6

Amendment  
Attorney Docket No. S63.2B-9919-US01

APR 23 2007

## Remarks

This Amendment is in response to the Office Action dated February 5, 2007. In which prosecution was again reopened. Reconsideration is requested.

Unnecessary language in the preambles of claims 1, 15, 17 and 21 has been deleted to remove possible confusion as to the proper antecedents in the body of the claims. At the same time step a) of these claims has been amended so that the polymer material is now positively recited at that location. No change in scope of these claims is intended.

Claims 2, 18 and 22 have been amended to positively recite the antecedent object upon which the repetition is performed. Again no change in the scope of these claims is intended.

Claims 1-11 and 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Healy et al (5,670,161) in view of Tower (5,868,783). The rejection is traversed.

The Office Action asserts:

Healy discloses in fig 5, a process for forming a stent having the limitations of claims 1- 23, including: the process comprises the step of forming a tubular stent of the polymer material (see col. 9, lines 22-46); the stent radially expanding to produce an expanded diameter stent (see col. 3, lines 9-45), and at least one time repeating of steps a-b are all performed prior to deployment of the stent in a body (see col. 7, lines 50-67), but Healy is silent regarding the step of annealing the expanded diameter stent to shrink its diameter to a reduced diameter.

The applicant does not agree. It is true that Healy fails to teach or suggest annealing an expanded diameter stent or tubular article to shrink its diameter to a reduced diameter. However it is *not* true that Healy otherwise discloses a process having the limitations of claims 1-23.

The stents of Healy are formed in the configuration for delivery (col. 8, line 66- col. 9, line 3). The stents may be formed in a number of ways (see e.g. col 8, lines 49-65 and col. 9 lines 17- 65). These processes do not involve radial expansion prior to stent delivery.

The Office Action cites col. 7, lines 50-67 apparently for the assertion that Healy teaches expansion prior to delivery, and apparently the repetition steps as well. The full text of this paragraph, which continues to col. 8, line 4, is reproduced below.

Application No. 10/037036  
Page 7

*Amendment*  
Attorney Docket No. S63.2B-9919-US01

Using the heating techniques described more fully below, the temperature of the polymer can be increased incrementally to a point near the glass-transition temperature of the copolymer, permitting the stent to enter a rubbery phase that takes advantage of a lower elastic modulus. In this phase, the stent may be plastically deformed and the shape stabilized prior to any viscoelastic behavior (such as creep, stress relaxation, strain recovery, or shrinkage) causes the stent to return to its unexpanded shape or to diminish in strength. Following expansion, the polymer is allowed to cool, but because plastic deformation has occurred, the stent remains open. Attempting to expand the stent of the present invention below the glass-transition temperature causes the stent to fracture as a result of its brittle or glassy characteristics below the glass-transition temperature. This could be potentially hazardous, depending upon whether and how the stent fractures as a result of being expanded improperly. Thus, controlled heating and expansion of the stent is important to the invention, as it results in a circumferential drawing of the extruded stent, helping to orient the copolymer molecules, and thereby enhances the modulus and strength of the materials, and ultimately the strength of the stent.

The Examiner has clearly misunderstood the paragraph. Regarding repetition, there is only one expansion step taught in this passage, one that occurs while the stent is heated, (*i.e. thermo-mechanical expansion of the stent*). There is nothing in this passage that can remotely be understood as teaching or suggesting a repetition of radial expansion steps on a stent.

Furthermore the Examiner has ignored the critical context statement which is found in the first sentence of the next paragraph (col. 8, lines 5-7, emphasis added):

*The thermo-mechanical expansion of the stent* is considered a processing step occurring *in situ and concomitant with deployment*.

That is, the thermo-expansion step described at col. 7, lines 50 - col. 8 line 4, is expressly taught as one that is performed in body at the time of deployment, not prior to deployment as recited in claims 1-11 and 15-24. Thus the only description in Healy of expanding the stents to an expanded diameter is in the context of expansion at the site of deployment. The stents are heated at the time of expansion (*see col. 3, lines 39-45 and col. 10, line 66 - col. 11, line 3, and col. 11, lines 32-51*). The heating allows the polymer material to plastically deform so that it retains its expanded configuration when cooled (*see col. 7, lines 50-61 where Healy teaches that following the heated expansion the stent is cooled and "remains open"*). This "remains open" feature would prevent delivery of the Healy stent if it occurred prior to the time the stent is deployed.

To the extent that the Examiner has cited col. 7, lines col. 7, lines 50-67 as showing repetition of "steps a-b," it seems that the Examiner has misunderstood the relevant repetition claims (claims 2, 18 and 22). Repetition of steps b) and c) is recited in those claims,

Application No. 10/037036  
Page 8

*Amendment*  
Attorney Docket No. S63.2B-9919-US01

not of step a). Moreover, the repetition is performed on the same article and, as such, is not met merely by performing the same steps once on a plurality of different stents or tubes. (If there was ever any question on this latter point, the amended language of claims 2, 18 and 22 unquestionably resolves the issue.) Still further as to these repetition claims, the application (page 9, lines 22-25) teaches that multiple expansions and annealings performed on the *same* tubular article can provide cumulatively increased radial orientation of the polymer material. This is a novel and non-obvious benefit not hinted at by anything in Healy or in Tower.

Furthermore as to claims 8 and 9, the above quoted portion of the Healy patent clearly and unambiguously teaches that the stent is to reach "a rubbery phase," at the time of expansion. This is the characteristic of polymer material above its glass transition temperature. Healy also teaches that "[a]ttempting to expand the stent of the present invention below the glass-transition temperature causes the stent to fracture." Taken together these statements clearly teach the skilled person that Healy's "near the glass-transition temperature" only pertains to temperatures that are actually *above* the glass transition temperature of the material. Healy's expansion step therefore does not meet the recitations of either of claims 8 or 9.

Regarding the combination of Healy with Tower, the Office Action is clearly mistaken in asserting that "Tower teaches annealing the expanded diameter stent ... to shrink its diameter to a reduced diameter ..." The cited passage of Tower pertaining to annealing (i.e. col. 3, lines 60-67 and col. 4, lines 1-7) describes annealing a malleable metal wire "prior to forming ... The wire before bending, *being in the fully annealed condition*, will retain whatever shape it is firmed [sic] into" (emphasis added). The annealing therefore is performed prior to formation of the wire into a stent configuration. This passage of the Tower patent therefore has nothing to do with annealing a stent or a tube. Still further, the passages of Tower asserted in the Office Action to pertain to stent diameter shrinkage (i.e. abstract, and col. 5, lines 31-39) actually pertain to the "axial" or "lateral" shrinkage which the stent undergoes during radial expansion (i.e. *diameter expansion*). These passages have nothing whatsoever to do with shrinkage of a stent, or tubular article, to a reduced diameter by annealing. The combination of Tower and Healy, therefore, does not meet the recitations of any of the rejected claims.

At least for the reasons given above withdrawal of the rejection of claims 1-11 and 15-24 for obviousness from Healy in view of Tower is respectfully requested.

Application No. 10/037036  
Page 9

*Amendment*  
Attorney Docket No. S63.2B-9919-US01

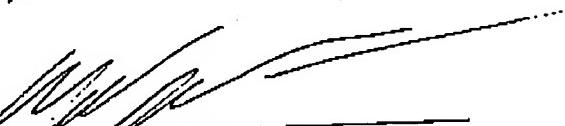
Claims 26-32 are new and present further aspects of the invention. Independent claim 26 recites an annealing step performed on an expanded diameter tubular article to shrink its diameter to a reduced diameter. Neither the Healy nor Tower patents teach such a step. At least for this reason claims 26-32 are seen to be both novel and non-obvious over the cited documents. Furthermore, claim 29 recites a repetition of the steps b) and c) on the tubular article, further steps which are not taught or suggested by either Healy or Tower. Similarly, claim 31 recites that step b) is performed at a temperature below the glass transition temperature of thermoplastic polymer material, another step not taught or suggested by either Healy or Tower.

In view of the foregoing amendments and remarks the application is believed to be in condition for allowance. Withdrawal of the outstanding rejections and allowance of the application is respectfully requested.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

By:

  
Walter J. Steinkraus  
Registration No.: 29592

Date: April 23, 2007

6109 Blue Circle Drive, Suite 2000  
Minnetonka, MN 55343-9185  
Telephone: (952) 563-3000  
Facsimile: (952) 563-3001

f:\wp\worldwjs\09919us01\_amd\_20070308.doc